UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,134	12/12/2007	Michael A. Ellsworth	PC32199A	7563

25533 7590 12/30/2009

PHARMACIA & UPJOHN
7000 Portage Road
KZO-300-104
KALAMAZOO, MI 49001

EXAMINER	
HURT, SHARON L	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
12/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSKala@Pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/593,134	ELLSWORTH ET AL.	
	Examiner	Art Unit	
	SHARON HURT	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/22/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 19-33 are pending and under examination. Claims 1-18 have been cancelled.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for **treating** testicular bovine viral diarrhea virus (BVDV) infection, does not reasonably provide enablement for **preventing** testicular BVDV infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are drawn to a method of preventing or controlling testicular bovine viral diarrhea virus infection in a susceptible male animal by administering to the animal an effective amount of a vaccine comprising: (a) a modified live type 1 BVDV; (b) a modified live type 2 BVDV; (c) an inactivated type 1 BVDV; or (d) an inactivated type 2 BVDV; or a combination thereof.

The first paragraph of 35 U.S.C. 112 states: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have

interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring ingenuity beyond that to be expected of one of ordinary skill in the art (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those In the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to preventing testicular BVDV infections in animals. The claim contains the term "**preventing**". The office interprets these terms as denoting absolute prevention of infection of even a single cell by a virus and absolute elimination of infection of any cell by a virus.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that the efficacy of therapeutics is dependent upon factors such as solubility of the drug, bioavailability at the target site, attainment of effective plasma concentrations, solubility in tissues, biotransformation, toxicity, rate of excretion or clearance, and in the case of antivirals, propensity for emergence of resistant strains (see Benet et al., pp. 3-32, in The Pharmacological Basis of Therapeutics, 8th ed., 1990, page 3, first paragraph; page 5, second column, last partial

paragraph, first two sentences; page 10, the paragraph bridging columns 1 and 2; page 18, the paragraph bridging columns 1 and 2; page 20, last full paragraph; and the paragraph bridging pages 20 and 21. The art further teaches that while there are antiviral agents which can reduce the incidence of or ameliorate the symptoms of viral infection, there are no treatment methods which can completely prevent viral infection in all cells in every subject and no antiviral agents which can completely eliminate infection in every cell of every subject.

The amount of direction or guidance present and the presence or absence of working examples: The disclosure is limited to an example of vaccinating cattle with Bovi-Shield® GOLD™ verus a placebo and challenge the cattle with type 1 BVDV or type 2 BVDV to test the effectiveness against testicular. There are no working examples drawn to absolute prevention of viral infection *in vivo* by employing the claimed method and no working examples showing absolute prevention of infection with viruses *in vivo*. Therefore, there is insufficient evidence to ascertain that the claimed compositions actually completely prevent or totally eliminate viral infection in animals.

The breadth of the claims and the quantity of experimentation needed: Because the art teaches a high degree of unpredictability in the ability of antivirals to completely prevent or eliminate viral infection, because the claims encompass absolute prevention and elimination of all virus infections, and because the specification fails to provide an enabling disclosure for absolute prevention or complete elimination, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 22 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Beer et al. (Veterinary Microbiology (2000) 77: 195-208).

Beer teaches a method of controlling BVDV infection in cattle comprising administering an inactivated vaccine containing BVDV I and II strains (type 1 and type 2) (Abstract and p. 197, Methods) (*as it relates to claims 19 and 31*). Beer teaches BVDV is a worldwide viral disease of cattle and the major economic losses due to BVDV infection are reduced fertility (p. 196, 1st full paragraph). Since cattle are at high risk for BVDV infection then Beer also reasonably meets the limitation of treating "an animal at increased risk of BVDV testicular infection" (*as it relates to claim 22*).

4. Claims 19-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Fulton et al. (Vaccine (2001) 19: 264-274).

Fulton teaches a method of controlling BVDV infection in cattle comprising administering commercial vaccines containing modified live virus (MLV) or inactivated BVDV (Abstract) (*as it relates to claim 19*). Fulton teaches the commercial vaccines were administered to healthy beef cattle of mixed sex (heifers and steers) less than one year old. A "steer" is a bull therefore Fulton meets the limitation of "the animal is a bull" (*as it relates to claims 20 and 21*).

Since cattle are at high risk for BVDV infection then Fulton reasonably meets the limitation of treating "an animal at increased risk of BVDV testicular infection" (*as it relates to claim 22*). Fulton teaches commercial vaccines comprising inactivated and modified live BHV-1, BVDV, PI-3V and BRSV (see Table 1, p. 265) (*as it relates to claims 23-24 and 31-33*). ViraShield®5 (Vaccine #3 in Table 1) comprises inactivated BVDV types 1 and 2 (*as it relates to claim 31*). Fulton teaches Triangle® comprises non-cytopathogenic virus (see Table 1 and p. 269, 3.1) (*as it relates to claim 27*).

Fulton teaches a commercial vaccine comprising MLV BVDV types 1 and 2 has been marketed in the US as Titanium® MLV Cattle Vaccines (p. 265, 1st partial paragraph). Titanium® 5 comprises MLV BHSV-1, BVDV type 1 and 11, PI3, BRSV (see product information or visit http://www.agrilabs.com/documents/Titanium_Detailer.pdf) (*as it relates to claims 25-30*). Titanium® product information lists IBR (infectious bovine rhinotracheitis), which is also known as bovine herpesvirus 1 (BHSV-1), as a component in the multi-vaccine. Titanium® comprises cytopathogenic virus (*as it relates to claims 26 and 28*). Therefore Fulton meets all the limitations of the instant claims.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M - F 8:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Hurt/
Examiner, Art Unit 1648
December 17, 2009

/Robert C. Hayes/, Ph.D.
Primary Examiner, Art Unit 1649